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FIRST NAMED INVENTOR APPLICATION NO. **FILING DATE** ATTORNEY DOCKET NO. 09/616,843 07/14/00 P NASH C150.12.3B **EXAMINER** HM12/0209 RICHARD O. BARTZ HUYNH, P 6750 FRANCE AVENUE SOUTH ART UNIT PAPER NUMBER SUITE 350 EDINA MN 55435 1644 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

02/09/01

•	Application No.	Applicant(s)
Office Action Summary	09/616,843	NASH ET AL.
	Examiner	Art Unit
	" Neon" Phuong Huynh	1644
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>Three</u> MONTH(S) FROM		
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status		
1)⊠ Responsive to communication(s) filed on <u>08 December 2000</u> .		
2a) This action is FINAL . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) <u>1-13</u> is/are pending in the application.		
4a) Of the above claim(s) <u>1-9,12 and 13</u> is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>10 and 11</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claims are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are objected to by the Examiner.		
11) The proposed drawing correction filed on is: a) approved b) disapproved.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).		
a) All b) Some * c) None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).		
Attachment(s)		
15) ⊠ Notice of References Cited (PTO-892) 16) □ Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) ⊠ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4	19) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)
Patent and Trademark Office		

Art Unit: 1644

DETAILED ACTION

- 1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Phuong N. Huynh, Art Unit 1644, Group 1640, Technology Center 1600.
- 2. Applicant's election with traverse of Group III, in Paper No. 3 is acknowledged. The traversal is on the grounds that the claimed subject matter of Groups II (claims 4-9), directed to a product may be joined with the claims of Group I (claim 1-3), directed to a method of making the antibody inhibitor and the claims of Group III and IV (claims 10-13), directed to a process of using the antibody inhibitor are not distinct. This is not found persuasive because the subject matter of the four Groups is patentably distinct for the reason set forth in Paper No. 2 and as shown by their divergent classification. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13are pending.

Claims 10 and 11 are being acted upon in this Office Action.

Claims 1-9 and 12-13 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

- 3. The reference AS on PTO 1449, initialed by the Examiner, was considered only to the extent of the first page, since subsequent page were not provided by the applicant. Further, pages number were missing for this reference. In order to have this reference printed on such resulting patent, author, title, date, volume and pertinent pages must be on PTO-1449 form.
- 4. Applicant should amend the first line of the specification to update the status of the priority documents, including provisional. For example, This Application claims priority under 35 U.S.C. 119 (e) of Provisional Application No. 60/201,268, filed on May 02, 2000.

Application/Control Number: 09/616,843

Art Unit: 1644

5. The instant claims 10-11 may not have the benefit under 35 U.S.C. 120 of the Provisional Application No. 60/143,985, filed on July 15, 1999 because the subject matter claimed in Claims 10-11 are not supported by this provisional application. Applicant is invited to verify that instant claims 10-11 have written support and enablement under 35 U.S.C 112, first paragraph, for the instant claims to Provisional Application No. 60/143,985, filed on July 15, 1999.

6. This application is required to be review and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the TM or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate correction is required in the specification, See, e.g. "22-24C" on the 4th line from the bottom of page 15; "(60°C(140°C) for 3.5 min)" on page 24; "The eggs were sampled using 250 μ of the whole egg" on pages 26 and 27; the table on page 29. It is suggested that "22-24 °C". Is it 60°F or 60°C and vice versus? Is it 250 μ m or 250 μ l? The OD values of the second and third columns were not in alignment with the test feed-additive and control feed of the first column.

It is noted that the content of page 21 and 22 of the instant specification is duplicated.

All pages of specification should be numbered consecutively with no missing or duplicate pages.

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
- 8. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, because the recitation of "particular targeted protein-wasting immunogen". The term "particular targeted

Application/Control Number: 09/616,843

Art Unit: 1644

protein-wasting immunogen" is indefinite because the metes and bounds of the immunogen/antigen that were used to inoculate the bird are ambiguous and ill defined.

It is suggested that Applicant amend the claims to "said protein-wasting immunogen is P antigen from P. anaerobius" as disclosed in example 7 on page 17 of the specification.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless -

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause *et al* (Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) in view of Tokoro *et al*. (US Pat No. 5,080,895, IDS; See entire document).

Krause et al teaches antibiotic monensin as a feed additive to decrease amino acid wasting caused by ruminal obligate amino acid-fermenting bacteria including, for example, Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium which are responsible for nutrition depletion and the growth of livestock (See entire document). However, adding monensin as a ruminant feed additive decreases the number of P. anaerobius and C. sticklandii but not the number of C. aminophilium in livestock.

Krause *et al.* differs from the claimed invention by not adding bird antibody (IgY) directed against *P. anaerobius*, *C. sticklandii and C. aminophilium* as a feed additive to improve the growth of livestock.

Tokoro *et al.* teaches adding bird antibody against various bacterial antigens including E. Coli as a feed additive to prevent diarrhea in livestock and the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to produce avian antibody as feed additive for livestock as taught by Tokoro et al by substituting the bacterial antigen from P anaerobius, C sticklandii, and C aminophilium

. Art Unit: 1644

as taught by Krause et al. One having ordinary skill in the art at the time the invention was made would have been motivated with a reasonable expectation of success to make *P anaerobius C sticklandii*, and *C aminophilium*-specific avian antibody as feed additive to promote the growth of livestock because the advantage of making avian antibody procedure is simple, efficient and inexpensive. Furthermore, antibody against *C. aminophilium* would decrease the number of *C. aminophilium* in livestock since monensin as feed additive fails to do so to improve the growth of livestock.

- 11. No claim is allowed.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
- 13. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

February 8, 2001

Patrick J. Nolan, Ph.D.

Patriet J. NOZ

Primary Examiner

Technology Center 1600